IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

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ESTATE OF TERI CASSEL, TERRY CASSEL, and RODNEY CASSEL-GEBHARD,

Plaintiffs,

v.

ALZA CORPORATION and JANSSEN PHARMACEUTICALS, INC.,

Defendants.

OPINION & ORDER

12-cv-771-wmc

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Teri Cassel passed away in 2009 while wearing two recently FDA-approved Duragesic brand patches containing the drug fentanyl. Ms. Cassel's estate and two of her sons brought this lawsuit against defendants ALZA Corporation ("ALZA") and Janssen Pharmaceuticals, Inc. ("Janssen"), alleging that manufacturing, marketing and design defects caused Ms. Cassel's death by accidental fentanyl overdose. Defendants moved for partial summary judgment on the design defect claims (dkt. #15), arguing that those claims are barred by "impossibility preemption" as articulated in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Wyeth v. Levine*, 555 U.S. 555 (2009), and, most recently, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). In response, plaintiffs moved to stay summary judgment briefing (dkt. #22) due to the fact-intensive nature of the preemption inquiry, a motion which this court granted (dkt. #28). The parties having now completed the necessary discovery and briefing on defendants' motion for partial summary judgment,[1] the court will deny defendants' motion for the reasons stated below.

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[1] Defendants also moved the court to revise its order staying summary judgment briefing for further factual development, pursuant to Rule 54(b), arguing that it is now clear that the design defect

## UNDISPUTED FACTS[2]

Defendant corporations designed and manufactured the first transdermal fentanyl patch drug for use in the United States under the brand name "Duragesic Reservoir Patch."[3] The Reservoir Patch contained the active ingredient fentanyl in a "form-fill-seal reservoir," within which the fentanyl was mixed in a gel with water and alcohol. There are four layers in a Reservoir Patch: (1) a backing layer of polyester film; (2) a drug reservoir of fentanyl and alcohol in a gel solution; (3) a rate-control membrane, which controls the rate of fentanyl delivery to the skin surface; and (4) an adhesive lawyer. Before use, a protective liner covering the adhesive layer is removed and discarded.

In 2009, the FDA approved a new fentanyl patch design that defendants submitted, called the "Duragesic Matrix Patch," which is the subject of this lawsuit. Unlike the Reservoir Patch, the Duragesic Matrix Patch contains no fentanyl gel. Rather, it contains only two functional layers protected by the liner: a backing layer and an adhesive layer, in which the fentanyl drug is contained.

Plaintiffs allege that the fentanyl patches that ALZA designed and manufactured and that Janssen sold, supplied and distributed lacked a rate-control membrane or laminated face adhesive layer, causing Teri Cassel's death by fentanyl overdose. Due to these alleged design defects, plaintiffs argue that the Duragesic Matrix Patch "fail[s] to provide adequate

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claims can be resolved as a matter of law. (*See* dkt. #30.) That motion will be denied, both because the court does not agree for the reasons articulated in this opinion and because the motion has been rendered boot by the issuance of this opinion itself.

[2] Defendants have proposed fourteen findings of fact in support of their motion for summary judgment. (Dkt. #17.) Plaintiffs have not responded to those findings of fact in any way, and so they will be deemed undisputed.

[3] The Reservoir Patch sold between 1990 and 2009.

protection against uncontrolled fentanyl delivery" and can produce lethal levels of fentanyl in patients.

## OPINION

Summary judgment is appropriate if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In ruling on a motion for summary judgment, the court views all facts and draws all inferences in the light most favorable to the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude summary judgment." *Id.* at 248.

The party moving for summary judgment bears the initial burden of informing the district court of the basis for its motion. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the initial burden is met, for an issue on which the nonmoving party will bear the burden of proof at trial, the nonmoving party must "go beyond the pleadings" and "designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324. It is not sufficient to "simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rather, the nonmoving party must produce "evidence . . . such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. If he fails to do so, "[t]he moving party is 'entitled to a judgment as a matter of law.'" *Id.* at 323.

Here, defendants argue that they are entitled to judgment as a matter of law on plaintiffs' design defect claims based on the doctrine of conflict preemption. This doctrine

has its roots in the Supremacy Clause, which states that federal law "shall be the supreme Law of the Land . . . anything in the constitution or laws of any State to the contrary notwithstanding." U.S. Const. art. VI, cl. 2. Thus, state law is preempted where (1) it is impossible for a party to comply with both state and federal law, *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); or (2) the state law is an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000). The first species of conflict preemption has come to be known as "impossibility preemption."

In both *Wyeth v. Levine* and *PLIVA, Inc. v. Mensing*, the United States Supreme Court discussed apparently incompatible duties under FDA regulations and state tort law. In *Wyeth*, the plaintiff was injured by an injection of the brand-name drug Phenergan. She argued that the label violated Vermont tort law by failing to warn about the dangers of Phenergan injection, even though it had been reviewed and approved by the FDA. The Supreme Court agreed, rejecting the defendant's preemption defense. *Wyeth*, 555 U.S. at 559-60. Specifically, the court held that the defendant could have complied with *both* state tort law and FDA rules by unilaterally improving the warning label -- an option granted to it by a "changes being effected" (CBE) regulation, which allowed a manufacturer to change a label without waiting for FDA approval if the change was to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." *Id.* at 568 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A), (C)). Although the FDA retained the authority to reject such changes, the Court held that "absent clear

evidence that the FDA would not have approved a change to Phenergan's label," impossibility preemption did not preclude the plaintiff's claims. *Id.* at 571.

In *Mensing*, the plaintiffs were injured by generic metoclopramide and argued, as in *Wyeth*, that the manufacturers were liable for violating their state law duty to provide adequate warning labels. Despite the similarities to *Wyeth*, the Supreme Court disagreed, holding that plaintiffs' claims were barred by impossibility preemption. The Court found that generic drug manufacturers face different duties than brand-name manufacturers, one of which is the "duty of sameness": generic drug labels must be the same at all times as the corresponding brand-name labels. *Mensing*, 131 S. Ct. at 2578; *see also, e.g.*, 21 U.S.C. § 355(j)(2)(A)(v). Because of this "duty of sameness," the Court explained, the generic manufacturers sued in *Mensing* lacked the option to make unilateral changes to their drug's label. 131 S. Ct. at 2575. Accordingly, the Court found that FDA law preempted any state law duty defendants had to ensure the label was adequate, since "it was not lawful under federal law for the Manufacturers to do what state law required of them" -- changing the generic metoclopramide's label to reflect the risk of injury -- as doing so would differentiate the generic label from the corresponding brand-name label. *Id.* at 2577.

Although the generic manufacturers in *Mensing* could have, at least theoretically, requested FDA assistance to lobby the *brand-name* manufacturers to change their labeling, the Court also found that doing so would not have satisfied state law requirements, since state law demanded a safer label, not communication about the possibility of one. *Id.* at 2577-78. Thus, the Court held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the

exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 2580-81.

In granting plaintiffs' motion to extend the time to respond to defendants' summary judgment motion, this court held that the *Wyeth* and *Mensing* decisions suggested a three-part test in analyzing impossibility preemption:

> First, the court must identify the steps a defendant should have taken to avoid liability under state tort law. Next, the court must determine as a matter of law whether federal law expressly *prohibited* the defendant from taking these steps. If the answer to this second question is 'No,' the court must determine whether the defendant has presented 'clear evidence' that the regulatory agency would have stepped in and exercised its discretionary authority to prohibit the defendant from taking the necessary steps under state law.

(Opinion & Order (dkt. #28) 4-5.)

Applying that test, this court found that (1) plaintiffs were alleging a duty to design the patches differently *before* FDA approval (rather than to change the design after the fact); and (2) no federal laws or regulations appear to have prohibited them from doing so. Accordingly, the court proceeded to step three, finding that the question of whether the FDA would have prevented defendants from redesigning the patch was a factual one, and granted plaintiffs' motion to stay summary judgment briefing to allow for additional discovery on this question. (*Id.* at 5-6.)

Since that decision, the Supreme Court has decided *Mutual Pharmaceutical Co., Inc. v. Bartlett*, which applied the *Wyeth* and *Mensing* analyses to a design-defect case. In *Bartlett*, the plaintiff was prescribed a generic form of an anti-inflammatory pain reliever known as sulindac. As a result, she developed an acute case of toxic epidermal necrolysis. At the time that she was prescribed sulindac, its label did not refer to the risks of toxic epidermal

necrolysis or the related condition Stevens-Johnson syndrome, though the label did warn that the drug could cause "severe skin reactions" and "fatalities." At trial, Bartlett prevailed on a design-defect claim, and the court of appeals affirmed, finding that neither the FDCA nor the FDA's regulations preempted that claim. Specifically, the court of appeals found that generic manufacturers facing design-defect claims could comply with both federal and state law by choosing not to make the drug at all. *Bartlett*, 133 S. Ct. at 2472.

The Supreme Court reversed, holding that impossibility preemption barred Bartlett's claims. It found that New Hampshire state law imposed a duty "to ensure that the products [manufacturers] design, manufacture, and sell are not 'unreasonably dangerous.'" *Id.* at 2474. That duty could be satisfied "either by changing a drug's design or by changing is labeling." *Id.* As for a redesign of the drug, the Court found that was not possible for two reasons: (1) the FDCA requires generics to have the "same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based"; and (2) sulindac is "chemically incapable" of being redesigned. *Id.* at 2475.

Since redesign was not an option, the Court examined whether Mutual Pharmaceutical Co. could have altered the drug's labeling to render it not "unreasonably dangerous," but concluded, as in *Mensing,* that "federal law prevents generic drug manufacturers from changing their labels." *Id.* at 2476. Thus, the Court held that "federal law prohibited Mutual from taking the remedial action required to avoid liability under New Hampshire law." *Id.* The Court also rejected the lower court's conclusion that Mutual could have complied with both state and federal law by simply exiting the market, holding that, "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" *Id.* at 2477 (quoting *Mensing*, 131 S. Ct. at 2579).

Defendants now argue that *Bartlett* stands for the proposition that "federal preemption bars any state-law claim, including design-defect claims, premised on a manufacturer's failure to market a drug with a new design feature that would constitute a 'major change' or render it a new drug, either of which requires prior FDA approval." (Mot. to Revise Order (dkt. #30) 3.) They specifically rely on the sentence in *Bartlett* reading: "once a drug – whether generic or brand-name – is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." *Bartlett*, 133 S. Ct. at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i)).[4] Since adding a rate-control membrane to the patch would have been by defendants' lights just such a "major change" requiring FDA approval, defendants were barred from the redesign that state law allegedly required.

As an initial matter, the court does not read *Bartlett* so broadly. In *Bartlett,* the Supreme Court found that designing sulindac differently was impossible for two specifically enumerated reasons, neither of which is true in this case: (1) generic drugs must have the same active ingredients, route of administration, dosage form, strength and labeling as their brand-name counterparts; and (2) sulindac is chemically incapable of being designed differently. *Id.* at 2475. Here, defendants are not subject to any such duty of sameness, since their patches are brand-name, and their own proposed findings of fact demonstrate that fentanyl patches are amenable to various designs. (*See* DPFOF (dkt. #17) ¶¶ 6-14.) Thus, at a minimum, *Bartlett* is factually distinct from this case.

[4] The court notes that this language is not, as defendants suggest, part of the *Bartlett* holding. It is in fact a citation to the Code of Federal Regulations that appears in the Supreme Court's overview of the applicable statutory scheme and regulations.

More importantly, the bulk of defendants' argument is premised on a mischaracterization of plaintiffs' theory of the case. Defendants may well be right that adding a rate-control membrane to their existing Duragesic Matrix Patch post-FDA approval would have been a "major change" under 21 C.F.R. § 314.70(b) that they could not undertake unilaterally. And certainly, the *Bartlett* Court held that federal law "does prevent [drug companies] from taking certain remedial measures." *Bartlett*, 133 S. Ct. at 2479. But as this court noted in its previous order, that argument "would only matter if defendants' tort lies solely in failing to redesign the patch *after* FDA approval." (Opinion & Order (dkt. #28) 6 (emphasis in original).) Plaintiff's theory here is that defendants had a duty to employ an alternative design – such as a design with a rate-control membrane, or a multi-laminate design -- from the beginning, *before* FDA approval. (*See* Pl.'s Resp. (dkt. #32) 9.) Thus, as this court noted in its previous order, defendants' emphasis on altering their patches *after* FDA approval is misplaced and does not entitle them to summary judgment.

Defendants do briefly address plaintiffs' actual design defect theory in their Reply, but those arguments are similarly unavailing. Essentially, defendants contend that it is irrelevant whether they could have initially created and submitted to the FDA a different design -- such as a multi-laminate patch or a matrix patch with a rate-control membrane -- when first seeking FDA approval in 2009. The reason, they argue, is because either of these other designs would still have had to procure initial FDA approval before introducing them into the market. In defendants' view, the "need to ask the FDA for its approval *before* marketing the new design . . . is dispositive of the preemption issue." (*See* Defs.' Reply (dkt. #41) 2 (emphasis in original).)

The court finds this argument unconvincing. As an initial matter, to credit it would effectively foreclose *all* design-defect claims against drug manufacturers, at least in systems imposing affirmative duties on manufacturers.[5] Under federal law, as defendants themselves acknowledge, "[n]o person shall introduce or deliver for introduction into interstate commerce *any* new drug, unless an approval of an application . . . is effective with respect to such a drug." 21 U.S.C. § 355(a) (emphasis added). Since defendants would find preemption wherever a manufacturer needs to ask for FDA approval before marketing, and since *all* new drugs require FDA approval before marketing, no drug manufacturer could *ever* be liable for a defectively designed product under defendants' interpretation of the doctrine. None of the impossibility preemption cases to date contemplates this wholesale preemption of state product liability claims, at least in the drug context. To the contrary, the Supreme Court in *Bartlett* specifically noted that "federal law establishes no safe-harbor for drug companies." 133 S. Ct. at 2479. To grant defendants' motion for summary judgment on this basis would credit a criticism in Justice Sotomayor's dissent, which the *Bartlett* Court expressly disavowed: it would "give[] pharmaceutical companies a right to sell a federally approved drug free from common-law liability." *Id.* at 2478 (quoting *id.* at 2483 (Sotomayor, J., dissenting)).[6]

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[5] The *Bartlett* Court "save[d] for another day the question whether a true absolute-liability state-law system could give rise to impossibility pre-emption." *Bartlett*, 133 S.Ct. at 2474 n.1. It recognized at the same time, however, that "most common-law causes of action for negligence and strict liability do not exist merely to spread risk, but rather impose affirmative duties." *Id.*

[6] Indeed, the case factually closest to this one that the court has been able to find, *Frazier v. Mylan Inc.*, 911 F. Supp. 2d 1285 (N.D. Ga. 2012), rejected just such a preemption defense in the context of design defect claims with respect to brand-name drugs, because the manufacturer "pointed to no federal requirement mandating that Pfizer's product be designed in a certain way or asserted that the FDA requires a certain design." *Id.* at 1295. Admittedly, this case was decided before *Bartlett*, but there is no pronouncement in *Bartlett* that conflicts with the reasoning in *Frazier*.

Given the current state of the law as articulated by the Supreme Court, this court holds to its original view of this case and the relevant test. Under plaintiffs' theory, state law required defendants to design their Duragesic Matrix Patches differently. *See* Wis. Stat. § 895.047(1)(a) (manufacturer liable for design defect if foreseeable risks of harm could have been reduced or avoided by adoption of reasonable alternative design, omission of which renders the product not reasonably safe). No federal law prohibited defendants from submitting a different design (or at least, defendants have pointed to none). Similarly, defendants have offered *no* evidence that the FDA would have exercised its authority to prohibit defendants from creating and submitting such a design for approval. The court, therefore, cannot say that defendants have met their burden to demonstrate as a matter of law the "demanding defense" of impossibility preemption. *See Wyeth*, 555 U.S. at 573.

ORDER

IT IS ORDERED that:

1) defendants ALZA Corporation and Janssen Pharmaceuticals, Inc.'s Motion for Partial Summary Judgment (dkt. #15) is DENIED.

2) defendants' Motion to Revise May 3, 2013 Order Denying Partial Summary Judgment on Design Defect as a Matter of Law (dkt. #30) is DENIED.

Entered this 5th day of March, 2014.

BY THE COURT:

/s/

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WILLIAM M. CONLEY
District Judge